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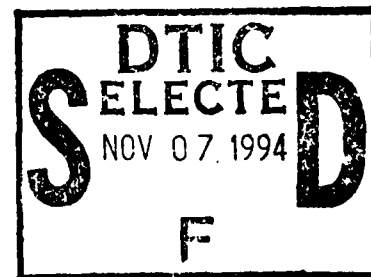
TITLE: DEVELOPMENT OF ULTRA LONG DURATION LOCAL ANESTHETIC
AGENTS IN A RAT MODEL

PRINCIPAL INVESTIGATOR: Mark Kline, CPT, MC

CONTRACTING ORGANIZATION: Combat Anesthesia Research
Pain Management/Anesthesia
Walter Reed Army Medical Center
Washington, DC 20307-5001

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Memorandum for LTC Dean E. Calcagni, M.D.
Director, Combat Casualty Research Program
USAMRDC

Subject: Annual Report for Clinical Investigation Protocol 2056A "Development of Ultra Long Duration Local Anesthetic Agents in a Rat Model" (FY 93)

1. Progress: We have previously demonstrated that lecithin-coated tetracaine microcrystals provide an ultra long duration local anesthetic effect of 44 hours in the rat tail. We have also previously demonstrated that this formulation is not toxic to skin tissues when placed intradermally. This year we were able to demonstrate that lecithin-coated tetracaine microcrystals do not cause peripheral neurotoxicity when placed directly on the sciatic nerve. In addition, initial data indicate that this formulation is not toxic to the spinal cord.

Initial trials with lecithin-coated bupivacaine microcrystals indicate that this preparation also has an ultra long duration local anesthetic effect, producing a 43 hour block in the rat tail. Clinical trials of this preparation in a human model are scheduled to begin in Jan 94.

2. Summary: Lecithin-coated tetracaine microcrystals provide an ultra long duration local anesthetic effect without causing toxicity to surrounding tissues or nerves. Lecithin-coated bupivacaine microcrystals also appear to have an ultra long duration local anesthetic effect, although tissue toxicity remains to be evaluated.

3. Publications:

B.H. Boedeker, MD, M.D. Kline, MD, M.E. Mattix, DVM, D.G. Dunn, DVM, D.H. Haynes, PhD, W.L. Mondy, BS, P.Z. Kelly, RN, E.W. Lojeski, DO: Peripheral neurotoxicity of lecithin-coated tetracaine microcrystals. *Anesthesiology* 79: A825, 1993

K.A. Burnham, MD, B.H. Boedeker, MD, M.D. Kline, MD, M.E. Mattix, DVM, J. Long, PhD, M.D. Calkins, MD, T. Rapacki, MD, D.H. Haynes, PhD: Spinal cord toxicity of lecithin-coated tetracaine microcrystals in the rat. Submission to ASRA.

M.D. Kline, MD, B.H. Boedeker, MD, K.A. Burnham, MD, M.D. Calkins, MD, D.H. Haynes, PhD: Lecithin-coated bupivacaine microcrystals produce ultra long duration local anesthesia. Submission to ASRA.

B.H. Boedeker, MD, E.W. Lojeski, DO, M.D. Kline, MD, D.H. Haynes, PhD: Ultra long duration local anesthesia produced by injection of lecithin-coated tetracaine microcrystals. Accepted for publication by The Journal of Clinical Pharmacology.

Mark D. Kline

Mark D. Kline, MD
CPT, MC
WRAMC

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